

IN THE CLAIMS:

1 – 67. (Cancelled)

68. (Original) The method of claim 68, wherein the agent is delivered through the blood vessel wall and into a localized region of the body.

69. (Original) The method of claim 68, wherein the blood vessel has a connecting side vessel in the region between the two occlusion devices, the side vessel connecting with a plurality of smaller vessels that form a flow restricting configuration, and wherein the agent is delivered through at least one of the smaller vessels and into a semi-localized region of the body.

70. (Original) The method of claim 68, wherein the outer catheter occlusion device is expanded prior to the inner catheter occlusion device.

71. (Original) The method of claim 68, wherein the inner catheter occlusion device is expanded prior to the outer catheter occlusion device.

72. (Original) The method of claim 68, further comprising using a guide wire previously positioned within the blood vessel to facilitate positioning of the inner and outer catheters within the blood vessel.

73. (Withdrawn) The method of claim 68, wherein positioning the inner and outer catheter within the blood vessel comprises:

positioning the inner catheter within the blood vessel; and

slidably advancing the outer catheter over the inner catheter and into position within the blood vessel.

74. (Original) The method of claim 74, further comprising:

advancing a guide wire into the blood vessel prior to positioning the inner catheter; and

slidably advancing the inner catheter over the guide wire and into position within the blood vessel.

75. (Withdrawn) The method of claim 74, further comprising positioning the inner catheter within the blood vessel with a stylet.

76. (Withdrawn) The method of claim 74, further comprising positioning the inner catheter within the blood vessel by advancing the inner catheter through the blood vessel using a guide wire integrated with the inner catheter.

77. (Withdrawn) The method of claim 68, wherein positioning the inner and outer catheter within the blood vessel comprises:

positioning the outer catheter within the blood vessel; and

slidably advancing the inner catheter within the outer catheter and into position within the blood vessel.

78. (Original) The method of claim 78, further comprising:

advancing a guide wire into the blood vessel prior to positioning the outer catheter; and

slidably advancing the outer catheter over the guide wire and into position within the blood vessel.

79. (Withdrawn) The method of claim 78, further comprising advancing the outer catheter into position within the blood vessel.

80. (Original) The method of claim 80, further comprising advancing the outer catheter into position within the blood vessel with a stylet located within the outer catheter.

81. (Withdrawn) The method of claim 80, wherein a distal region of the outer catheter has a pre-formed curve to facilitate advancement of the outer catheter within the blood vessel.

82. (Original) The method of claim 82, further comprising straightening the pre-formed curve of the outer catheter with a dilator to facilitate advancement of the outer catheter.

83. (Original) The method of claim 68, wherein the agent has characteristics that promote angiogenesis.

84. (Original) The method of claim 68, wherein the agent has characteristics that promote myogenesis.

85. (Original) The method of claim 68, further comprising monitoring the pressure during delivery of the agent.

86. (Original) The method of claim 87, further comprising regulating the pressure during delivery of the agent with a pressure regulator.

87. (Original) The method of claim 87, wherein the pressure is regulated passively.

88. (Original) The method of claim 87, wherein the pressure is regulated actively with a pressure monitoring lumen providing a fluid pressure feedback from the region of the blood vessel between the occlusion devices to the pressure regulator.

89. (Original) The method of claim 68, wherein the blood vessel is a vein located within the heart.

90. (Original) The method of claim 90, wherein the blood vessel is the anterior interventricular vein (AIV).

91. (Original) The method of claim 68, further comprising delivering radio opaque dye to the blood vessel prior to delivering the agent.

92. (Original) The method of claim 68, wherein the agent is delivered through the open distal end of the outer catheter.

93. (Original) The method of claim 68, wherein the agent is delivered through an opening in the inner catheter located between the two occlusion devices.

94. (Original) A method of infusing an agent into a localized or semi-localized region of the body, comprising:

advancing a guide wire into the blood vessel;

slidably advancing a catheter over the guide wire using a lumen within the catheter;

positioning the catheter within a blood vessel, the catheter having a first and a second occlusion device associated therewith, wherein the first occlusion device is located distally from the second occlusion device;

expanding the occlusion devices such that the blood vessel is occluded by the first occlusion device in a first location and by the second occlusion device in a second location proximal to the first location;

delivering an agent from the lumen and into the region of the blood vessel located between the two expanded occlusion devices at a pressure sufficient to infuse the agent into a region of the body external to the blood vessel.

95. (Withdrawn) The method of claim 95, wherein the agent is delivered through the blood vessel wall and into a localized region of the body.

96. (Withdrawn) The method of claim 95, wherein the blood vessel has a connecting side vessel in the region between the two occlusion devices, the side vessel connecting with a plurality of smaller vessels that form a flow restricting configuration, and wherein the agent is delivered through at least one of the smaller vessels and into a semi-localized region of the body.

97. (Withdrawn) The method of claim 95, wherein the agent is delivered from the lumen within the catheter through an opening in the catheter located between the two occlusion devices.

98. (Withdrawn) The method of claim 95, wherein the occlusion devices are balloons.

99. (Withdrawn) The method of claim 99. further comprising expanding the balloons by passing an inflation medium through a lumen in communication with each of the two occlusion devices.

100. (Withdrawn) The method of claim 95, further comprising withdrawing the guide wire prior to delivering the agent.

101. (Withdrawn) The method of claim 101, wherein a distal end of the catheter includes a valve configured to allow the guide wire to pass therethrough.

102. (Withdrawn) The method of claim 102, further comprising at least partially closing the valve upon withdrawal of the guide wire.

103. (Withdrawn) The method of claim 102, wherein the valve is configured such that the pressure exerted by the agent on the valve during delivery causes the valve to seal.

104. (Withdrawn) The method of claim 95, further comprising delivering a radio opaque substance to monitor the infusion of the agent into the region of the body.

105. (Withdrawn) The method of claim 95, further comprising delivering a radio opaque substance with the agent to monitor the infusion of the agent into the region of the body.

106. (Withdrawn) A method of infusing an agent into a localized or semi-localized region of the body, comprising:

positioning an inner catheter and an outer catheter within a blood vessel, the outer catheter having an open distal end and configured to slidably receive the inner catheter, the outer catheter having an occlusion device associated therewith and the inner catheter having a first and a second occlusion device associated therewith with the first occlusion device located distally from the second occlusion device;

positioning at least one of the inner catheter occlusion devices distally from the distal end of the outer catheter;

expanding at least two of the occlusion devices such that the blood vessel is occluded by one occlusion device in a first location and by another occlusion device in a second location proximal to the first location, wherein the occlusion device in the first location is either the first inner catheter occlusion device or the second inner catheter occlusion device if the second device is positioned distally from the distal end of the outer catheter, and wherein the occlusion device in the second location is either the outer catheter occlusion device or the proximally located inner catheter occlusion device if that device is positioned distally from

the distal end of the outer catheter and not used to occlude the vessel in the first location;

delivering an agent in the region of the blood vessel located between the at least two expanded occlusion devices at a pressure sufficient to infuse the agent into a localized region of the body.

107. (Withdrawn) The method of claim 107, wherein the agent is delivered through the blood vessel wall and into a localized region of the body.

108. (Withdrawn) The method of claim 107, wherein the blood vessel has a connecting side vessel in the region between the at least two occlusion devices, the side vessel connecting with a plurality of smaller vessels that form a flow restricting configuration, and wherein the agent is delivered through at least one of the smaller vessels and into a semi-localized region of the body.

109. (Withdrawn) The method of claim 107, wherein the distally located first inner catheter occlusion device is occludes the vessel in the first location and the outer catheter occlusion device occludes the vessel in the second location.

110. (Withdrawn) The method of claim 110, wherein the proximally located second inner catheter occlusion device remains unexpanded during delivery of the agent.

111. (Withdrawn) The method of claim 110, wherein the agent is delivered through the open distal end of the outer catheter.

112. (Withdrawn) The method of claim 110, further comprising monitoring the pressure in the region of the blood vessel located between the at least two expanded occlusion devices during delivery of the agent.

113. (Withdrawn) The method of claim 107, wherein the distally located first inner catheter occlusion device is occludes the vessel in the first location and the proximally located second inner catheter occlusion device occludes the vessel in the second location.

114. (Withdrawn) The method of claim 114, wherein the outer catheter occlusion device is left unexpanded during delivery of the agent.

115. (Withdrawn) The method of claim 115, wherein the agent is delivered through an aperture in the inner catheter located between the two occlusion devices associated with the inner catheter.

116. (Withdrawn) The method of claim 114, further comprising monitoring the pressure in the region of the blood vessel located between the at least two expanded occlusion devices during delivery of the agent.

117. (Withdrawn) A kit for providing a catheter system for use in the delivery of an infusion agent to an isolated blood vessel region, comprising:

a first catheter having a proximal end, a distal end and a first expandable occlusion device associated therewith, and a second catheter having a proximal end and a distal end and a second expandable occlusion device associated therewith, wherein the first catheter is configured to expand the first occlusion device distally of the second occlusion device on the second catheter, the first catheter being slidably housed within a first lumen in the second catheter such that the distance between the first and second occlusion devices may be varied, the occlusion devices being expandable to engage a wall of a blood vessel thereby substantially isolating an interior region of a desired extent between the first and second occlusion devices, wherein the first lumen is configured to deliver an agent to the isolated interior region; and

a pressure regulator configured to regulate the fluid pressure of the agent.

118. – 130. (Cancelled)

131. (Withdrawn) The method of claim 131, wherein the blood vessel comprises the anterior interventricular vein (AIV).

132. (Withdrawn) The method of claim 132, wherein the smaller vessels are tributaries.

133. (Withdrawn) The method of claim 133, wherein positioning the catheter comprises advancing the catheter through a coronary sinus and a great cardiac vein and into the AIV.

134. (Withdrawn) The method of claim 133, wherein the pressure is sufficient to infuse the agent through the vessel wall of the AIV and into the semi-localized region.

135. (Withdrawn) The method of claim 135, wherein the plurality of tributaries includes at least one venule.

136. (Withdrawn) The method of claim 131, wherein the catheter comprises a closed distal tip that covers the distal end of the guide wire.

137. (Withdrawn) The method of claim 131, further comprising positioning a guide wire in proximity with the infusion site prior to positioning the catheter.

138. (Withdrawn) The method of claim 138, wherein the step of positioning the catheter comprises routing the catheter over the guide wire using a lumen disposed within the catheter.

139. (Withdrawn) A method of infusing an agent into a localized or semi-localized region of the body, comprising:

positioning a catheter within a blood vessel, the catheter having an occlusion device associated therewith, wherein the occlusion device has an axially indented portion in a middle section of the device;

expanding the occlusion device to occlude the blood vessel and create an isolated space in the blood vessel adjacent to the axially indented portion of the occlusion device;

delivering an agent in the space of the blood vessel adjacent to the indented portion of the occlusion device and not in contact with the indented portion of the occlusion device at a pressure sufficient to infuse the agent into a region of the body.

expanding the occlusion device.

140. – 153. (Cancelled)

154. (Withdrawn) The method of claim 154, wherein the desired level is chosen to avoid injury to a patient.

155. (Withdrawn) The method of claim 155, wherein the pressure is regulated actively.

156. (Withdrawn) The method of claim 156, wherein the pressure is regulated with a pressure regulator coupled with the first and second lumens.

157. (Withdrawn) The method of claim 154, further comprising expanding a second occlusion device distally from the first to isolate a portion of the blood vessel defined by the first and second occlusion devices.

158. (Withdrawn) An injection system for pressure regulated injection of a fluid into an isolated blood vessel region having a pressure regulator comprising:

- a housing having a lumen located between a fluid input and a fluid output;
- a spool movably disposed within the housing, the spool having a first end, a second end and a through-hole alignable with the lumen such that fluid can pass through the lumen only when the through-hole is at least partially aligned with the lumen; and

- a fluid pressure feedback coupled with the spool and configured to monitor the fluid pressure at the isolated blood vessel region and move the spool at least partially out of alignment with the lumen when the fluid pressure at the blood vessel exceeds a predetermined level.

159. – 217. (Cancelled)